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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,235	06/22/2001	Joan P. Blonder	42830-00234	8106
25231	7590	11/16/2004	EXAMINER	
MARSH, FISCHMANN & BREYFOGLE LLP 3151 SOUTH VAUGHN WAY SUITE 411 AURORA, CO 80014			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/888,235

**Applicant(s)**

BLONDER ET AL.

**Examiner**

Bao Qun Li

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9-31,33-37,39-44,148 and 149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9-31,33-37,39-44,148 and 149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to amendment, paper No. 20, filed 08/10/04. Claim 1 has been amended. Claim 38 has been canceled. New claims 148-149 have been added. The status of claims is summarized as following: Claims 2-3, 8, 31, 38, and 45-147 were canceled. Claims 1, 4-7, 9-30, 32-37, 39-44 and 148-149 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 5-7, 9-11, 12, 15, 43-44 and 148-149 are still rejected under 35 U.S.C. 102(b) as anticipated by Winter et al. (Infection and Immunity 1988, Vol. 56, No. 11, pp. 2808-2827) in light of teaching of Allison A (METHODS 1999, Vol. 19, pp. 87-93), Viegas et al. (a: US Patent No. 5,300,295A).

3. Applicants traverse the 102 (b) rejection made by the previous Office Action over the prior art Winter et al. in light of teaching of Allison A (METHODS 1999, Vol. 19, pp. 87-93), Viegas et al. (a: US Patent No. 5,300,295A) and submit that since applicants amend claim 1, the cited prior art does not teach the every limitation as claim 1 amended. Therefore, the rejection should be mooted.

4. Applicants' argument has been fully considered; however, it is not found persuasive because Winter et al. do teach every limitations of amended claim 1. Applicants attention is directed to the 1<sup>st</sup> col. of page 2810, in section of (iii), the examiner notice that even the reference by Winter et al. along teaches every limitation of claimed invention. Winter et al.

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teaches a method for immunizing a mouse model comprising administering each mouse a 100  $\mu$ l of a vaccine composition comprising 10  $\mu$ g of antigen, 2.5  $\mu$ g of reverse temperature copolymer L121 (5%), 10  $\mu$ g/ adjuvant MDP (10%), 5  $\mu$ l of sequalane and 95  $\mu$ l of PBS-Tween (Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products). Because the proportions of major active components, which exhibit the enhanced immune response for the claimed composition including an antigen, copolymer, and adjuvant, are all within the ranges of major active components as claim 1 drafted, the prior art anticipate the rejected claims. Therefore, the claimed invention is anticipated by the cited reference.

5. Regarding to the limitation of percentage of the aqueous liquid solvent, MPEM cites: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); and In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes, which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). Therefore, it would have been obvious for a person with ordinary skill in the art to make a composition **Within Prior Art Conditions or Through Routine Experimentation** absence unexpected result.*

6.

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***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li M.D.

11/14, 2004

  
JAMES HOUSEL 11/15/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600